

## **DETAILED ACTION**

### ***Status of the Application***

1. Claims 1-30 have been examined in this application. This communication is a Final Office Action in response to the "Amendment" and "Remarks" filed on February 1, 2008.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 6-20 and 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 5,788,669 to Peterson in view of US Patent Number 5,713,856 to Eggers in view of Official Notice.

(A) As per claim 1, Peterson discloses a method for creating a library of pump data on a computer having a database, the pump data being organized into sets of program data, each set of program data being available for batch downloading to a medical pump and including data items for controlling operation of the medical pump, the method comprising:  
the plurality of data items forming a set of program data, (col. 4, lines 10-18 and lines 36-53).

Peterson teaches patient-specific parameters (Col. 1, Ln. 20-21). In Peterson the memory is within the pump (Figure 1 and Col. 3, Ln. 50-65).

Peterson does not explicitly disclose at least some of the data items establishing parameters for controlling operation of a medical PUDP entering a plurality of data items into a database on the computer.

However, Eggers discloses at least some of the data items establishing parameters for controlling operation of a medical pump (i.e. drug libraries customized for each user ...) (col. 10, line 62 - col. 11, line 45) entering a plurality of data being patient-specific data items into a database on the computer, and assigning at least one data key to the set of program data, the data key identifying the set of program data (i.e. drug libraries customized for each user ...)(col. 10, line 62 - col. 11, line 45). Eggers also teaches the following: batch-downloading the plurality of data items into the memory within the pump, at least some of the data items batch-downloaded into memory being patient-specific data items and controlling operation of the pump based on one or more data items (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 7). (Note: The Examiner takes the position that the step of downloading the library of data wherein each drug library can be customized for each user is equivalent to batch-downloading data for a specific patient. In other words, a user in Eggers can be a patient). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include at least some of the data items establishing parameters for controlling operation of a medical pump, entering a plurality of data items into a database on the computer as disclosed by Eggers within the Peterson system for the motivation of downloading complicated drug delivery profiles to the system (col. 2, lines 3-10 and col. 11, lines 14-20). Peterson and Eggers do not explicitly disclose assigning at least one data key to the set of program data, the data key identifying the set of program data.

However, the Examiner takes official notice that it was well known in the database arts to assign identifiers to data sets. The purpose of using identifiers was to locate the particular data that is to be utilized by a user or program. It would have been obvious to one of ordinary skill in the art at the time of Applicants invention to include assigning at least one data key to the set of

program data, the data key identifying the set of program data within Peterson and Eggers for the motivation stated above.

(B) As to claim 2, Peterson does not explicitly disclose the method of claim 1 wherein the acts of:

entering a plurality of data items into a database includes entering the plurality of data items into a program data record in the database.

However, Eggers discloses entering a plurality of data items into a database includes entering the plurality of data items into a program data record in the database (i.e. drug library (Col. 2, Ln. 3-10 and Col. 11, Ln. 14-26). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include entering a plurality of data items into a database includes entering the plurality of data items into a program data record in the database as disclosed by Eggers within the Peterson system for the motivation of downloading complicated drug delivery profiles to the system (col. 2, lines 3-10 and col. 11, lines 14-2). Peterson and Eggers do not explicitly disclose assigning at least one data key to the set of program data includes entering the data key into a data key record and linking the data key record to the program data record.

However, the Examiner takes official notice that it was well known in the database arts to assign identifiers to data sets and linking data key records to application programs.. The purpose of using identifiers was to locate the particular data that is to be utilized by a user or program. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to include assigning at least one data key to the set of program data includes entering the data key into a data key record and linking the data key record to the program data record within Peterson

and Eggers for the motivation stated above.

(C) As to claim 3, Peterson does not explicitly disclose the method of claim 2 wherein further including entering an identification code selected from the group consisting essentially of a patient I.D., a therapy I.D., and a fluid I.D., wherein the patient I.D. is a code identifying a patient, the therapy I.D. is a code identifying a therapy administered using a medical pump, and the fluid I.D. is a code identifying a fluid that is administered using a medical pump.

However, Eggers discloses further including entering an identification code selected from the group consisting essentially of a patient I.D., a therapy I.D., and a fluid I.D., wherein the patient I.D. is a code identifying a patient, the therapy I.D. is a code identifying a therapy administered using a medical pump, and the fluid I.D. is a code identifying a fluid that is administered using a medical pump (col. 10, line 62 - col. 11, line 7). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include entering an identification code selected from the group consisting essentially of a patient I.D., a therapy I.D., and a fluid I.D., wherein the patient I.D. is a code identifying a patient, the therapy I.D. is a code identifying a therapy administered using a medical pump, and the fluid I.D. is a code identifying a fluid that is administered using a medical pump as disclosed by Eggers within the Peterson system for the motivation of downloading complicated drug delivery profiles to the system (col. 2, lines 3-10 and col. 11, lines 14-20).

(D) As to claim 6, Peterson in view of Eggers disclose a computer storage medium contain a library of pump data, the computer storage medium be created by the method set forth in claim 1.

(E) Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson

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in view Eggers in view of Official Notice as applied to claim 3 above, and further in view of “Acute Health Solutions’ DoseWatch to use Multum's MediSource 'thereinafter MediSource) and Eggers as applied to claim 3 above, and further in view of “Acute Health Solutions”” DoseWatch to use Multum's MediSource (hereinafter Medisource).

As to claim 4, Peterson does not explicitly disclose the method of claim 3 wherein the computer is in data communication with a scanner, the method further comprising.

scanning a bar code with the scanner; and

entering the bar code into the computer, wherein the act of assigning at least one data key to the

set of program data includes assigning the bar code to the set of program data.

However, MediSource discloses wherein the computer is in data communication with a scanner, the method further comprising.

scanning a bar code with the scanner; and entering the bar code into the computer, wherein the act of assigning at least one data key to the set of program data includes assigning the bar code to the set of program data (see abstract and page 2, paragraph 3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein the computer is in data communication with a scanner, the method further comprising: scanning a bar code with the scanner; and entering the bar code into the computer, wherein the act of assigning at least one data key to the set of program data includes assigning the bar code to the set of program data as disclosed by MediSource with the combined system of Peterson, Eggers and Official Notice for the motivation to insure association of the drug and concentration with a pump rate and an infusion amount (Abstract).

As to claim 5, Peterson does not explicitly disclose the method of claim 3 wherein the computer is in data communication with a medical pump, the method further comprising uploading a set of program data items from the pump.

However, MediSource discloses wherein the computer is in data communication with a medical pump, the method further comprising uploading a set of program data items from the pump (Abstract and Page 2). It would have been obvious to one of ordinary skill in the art at the time of the invention to include a computer which is in data communication with a medical pump, the method further comprising uploading a set of program data items from the pump as disclosed by MediSource within the Peterson system for the motivation of insuring association of the drug and concentration with a pump rate and an infusion amount (Abstract).

(F) As per claims 7-20 and 23-24, these claims are substantially similar to claims 1-6 and are rejected on the same basis.

(G) Claims 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson in view of Eggers.

As per claim 26, Peterson teaches a pump for infusing fluid into a patient (Peterson: Figure 1 and Col. 3, Ln. 50-65), the pump comprising:

- a housing (Figure 1 and Col. 3, Ln. 50-65);
- a pump mechanism positioned within the housing (Figure 1 and Col. 3, Ln. 50-65);
- memory positioned within the housing and configured to store a plurality of data items being patient-specific data items forming a set of program data, at least some of the data items establishing patient-specific parameters for controlling operation of a medical pump (Figure 1; Col. 1, Ln. 1-21 and Col. 3, Ln. 50-65)

and multiple program modules (Col. 3, Ln. 56-65 and Col. 4, Ln. 54-57).

Peterson does not explicitly disclose at least some of the data items establishing parameters for controlling operation of a medical PUDP entering a plurality of data items into a database on the computer.

However, Eggers discloses at least some of the data items establishing parameters for controlling operation of a medical pump (i.e. drug libraries customized for each user ...) (col. 10, line 62 - col. 11, line 45) entering a plurality of data items into a database on the computer, and assigning at least one data key to the set of program data, the data key identifying the set of program data (i.e. drug libraries customized for each user ...)(col. 10, line 62 - col. 11, line 45). Eggers also teaches the following: batch-downloading the plurality of data items, at least some of the data items batch-downloaded being patient-specific data items, into the memory within the pump and controlling operation of the pump based on one or more data items (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 7). (Note: The Examiner takes the position that the step of downloading the library of data wherein each drug library can be customized for each user is equivalent to batch-downloading data for a specific patient. In other words, a user in Eggers can be a patient). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include at least some of the data items establishing parameters for controlling operation of a medical pump, entering a plurality of data items into a database on the computer as disclosed by Eggers within the Peterson system for the motivation of downloading complicated drug delivery profiles to the system (Eggers: Col. 2, lines 3-10 and col. 11, lines 14-20). Peterson and Eggers do not explicitly disclose assigning at least one data key to the set of program data, the data key identifying the set of program data.

(H) As per claim 27, in Peterson the program data includes the delivery rate for the patient (Peterson: Col. 4, Ln. 47-53).

(I) As per claim 28, in Peterson the program data identifies a therapy name (Peterson: Col. 4, Ln. 47-53).

(J) As per claims 29-31, are these claims are substantially similar to claims 1-20, 23-24 and 26-28, above, are rejected on the same basis.

(K) As per claim 32, the combined teachings of Peterson in view of Eggers teaches that the plurality of data items includes at least one data item selected from the group consisting of data items related to delivery schedules, medication doses, and boluses (Eggers: Col. 10, Ln. 62-66). The motivation for making this modification to Peterson is the same as that set forth above, in the rejection of Claim 26.

#### ***Response to Arguments***

4. Applicant's arguments filed February 1, 2008 have been fully considered but they are not persuasive.

Applicants argue that Eggers does not teach downloading patient-specific data because drug dosages, among other items, are not patient-specific data. However, dosages are in fact patient specific data. For example, a toddler has a dosage requirement of a medicine which is usually different from an adult, therefore, the Office takes the position that a dosage is in fact a patient-specific data item. Because Eggers teaches patient-specific data items, the applicants arguments with regards to the deficiencies in the other references (i.e. Peterson, Klein, Official Notice and "Acute Health Solutions") are rendered moot because applicants essentially argue



that these references do not teach patient-specific data. However, as just set forth, patient-specific data is taught by Eggers.

### ***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

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Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek Koppikar

4/16/2008

/Robert Morgan/

Primary Examiner, Art Unit 3626